

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 26 JAN. 2005

WIPO PCT

Applicant's or agent's file reference <b>HUM254WIOT02</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416																								
International application No. <b>PCT/US04/00541</b>	International filing date (day/month/year) <b>12 January 2004 (12.01.2004)</b>	Priority date (day/month/year) <b>13 January 2003 (13.01.2003)</b>																								
International Patent Classification (IPC) or national classification and IPC <b>IPC(7): A61K 31/56 and US Cl.: 514/177, 178, 182</b>																										
Applicant <b>HUMANETICS CORPORATION</b>																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																								
<input type="checkbox"/>	Box No. II	Priority																								
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																								
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																								
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																								
<input type="checkbox"/>	Box No. VI	Certain documents cited																								
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																								
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																								
Date of submission of the demand <b>15 December 2004 (15.12.2004)</b>	Date of completion of this report <b>03 January 2005 (03.01.2005)</b>																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  <b>Sreenivasan Padmanabhan</b> Telephone No. 703-308-1235																									

Jean Proctor  
Paralegal Specialist

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/00541

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-4 as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the claims:

pages 5 as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the drawings:

pages NONE as originally filed/furnished

pages\* NONE received by this Authority on \_\_\_\_\_

pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."  
Form PCT/IPEA/409 (Box No. I) (January 2004)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/00541**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-9</u>	NO
Industrial Applicability (IA)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-9 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach a method of achieving accelerated fat loss comprising administration of a fat loss accelerating agent to a dieting mammal wherein the fat loss accelerating agent is 7-oxo DHEA or a pro-drug thereof incapable of in vivo conversion to testosterone.

Claims 1-9 lack an inventive step under PCT Article 33(3) as being obvious over PATRIDGE et al. (US 5,296,481).

PATRIDGE et al. teach a method for controlling weight gain or promoting weight loss in a human subject comprising daily oral administration comprising an amount of the compound, 7-oxo DHEA. (abstract, column 4, lines 61-65, column 5, lines 32-43, column 10, lines 1-3 and columns 11-12, claims 3 and 6). PATRIDGE et al. teach 7-oxo DHEA and the derivatives thereof wherein at least one of the hydroxyl group is esterified with an acid. (column 1, lines 60-65). Patridge et al. teach 7-oxo DHEA can be synthesized from the 7-one acetate and purified by employing the deesterification and purification steps. (column 3, lines 28-47). It would have been obvious to one of ordinary skill in the art to employ 7-oxo DHEA to achieve accelerated fat loss in dieting mammal since PATRIDGE et al. teach that active agent is useful for controlling weight gain or promoting weight loss. One would have been motivated to administer 7-oxo DHEA to dieting mammal in order to achieve weight loss generally includes fat loss as taught by PATRIDGE et al.

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus a method of achieving accelerated fat loss comprising administration of a fat loss accelerating agent to a dieting mammal wherein the fat loss accelerating agent is 7-oxo DHEA has industrial applicability because the subject matter claimed can be made or used in pharmaceutical industry.